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In the Supreme Court

OF THE

United States

OCTOBER TERM, 1978

No. 78-1850

JAMES ROBERT PRIVITERA, JR.,
Petitioner,

vs.

THE STATE OF CALIFORNIA,
Respondent.

On Petition for a Writ of Certiorari to the Supreme Court of California

BRIEF AMICUS CURIAE OF THE AMERICAN CANCER SOCIETY, CALIFORNIA DIVISION, INC., IN OPPOSITION TO THE PETITION FOR CERTIORARI

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STATEMENT OF INTEREST OF AMICUS CURIAE

Amicus curiae is a chartered division of the American Cancer Society, Inc. ("the Society"). Briefly stated the American public and the medical profession rely on the Society, and its 58 chartered Divisions and 2,964 local Units, to provide the most up-to-date and accurate information about cancer. In many cases early and effective treatment of cancer is a life and death matter. One of the major concerns expressed by the public and the medical profession in questions addressed to the Society pertains to unproven

methods of cancer treatment. To respond to the need for information in this area the Society has established a committee on unproven methods and maintains one of the world's largest reference centers for the collection and dissemination of data concerning cancer. To further its obligation to the public and the medical profession to uncover and disseminate the facts relating to unproven methods of cancer treatment, the Society participated as amicus curiae in the proceedings before the California Supreme Court, which resulted in the decision which is the subject of the present petition for writ of certiorari.

Dr. Privitera's petition challenges the existing statutory protection against unproven methods of cancer treatment contained in state and federal drug laws. If the current requirements of safety and efficacy fall, the consumer and the practicing physician will be deprived of the first line of defense against ineffective drugs. It is still true that:

> . . . There is no way of measuring the needless suffering, the money innocently squandered, and the protraction of illnesses resulting from the use of . . . ineffective drugs.
>
> The physician and consumer should have the assurance from an impartial scientific source that any drug or therapeutic device on the market today is safe and effective for its intended use. . .[1]

The impact of the California Supreme Court's decision, in *People v. Privitera*, 23 Cal.3d 697 (1979), which prevents

[1]Statement by John F. Kennedy to Congress, March 15, 1962, in support of the 1962 Amendments to the Federal Food, Drug and Cosmetic Act. 108 Cong. Rec. 3907; 1962 U.S. Code Cong. & Admin. News at 4143.

circumvention of state and federal drug standards of safety and efficacy by a "right of privacy" rationale, will obviously affect the Society in its role as a primary source of information for the general public and the medical profession for accurate information on unproven methods of cancer treatment.

In sustaining the validity of California Health and Safety Code § 1707.1, the California Supreme Court has effectively closed one of the floodgates that would encourage the marketing of an unproven cancer treatment in California, and elsewhere—the right of privacy rationale. The decision affirms a reasonable pre-market standard. It protects victims of cancer, who when confronted with a life-threatening illness are particularly susceptible to cures promised by use of a worthless, and therefore unsafe and dangerous drug. The Society's interest lies in speaking out for the continuation of the proper balance of manufacturer and consumer interest which currently exists in the statutory scheme regulating drugs. It would be a great disservice to the public if a decision affirming this balanced regulatory scheme was undermined by a petition which, as demonstrated below, is unsound as a matter of law.

REASONS FOR DENYING THE PETITION FOR WRIT OF CERTIORARI

I.

THE CALIFORNIA SUPREME COURT HAS DECIDED THE RIGHT OF PRIVACY ISSUE IN ACCORDANCE WITH THE APPLICABLE DECISIONS OF THIS COURT

The interpretation and application of *Planned Parenthood of Missouri v. Danforth*, 428 U.S. 52 (1976); *Roe v. Wade*, 410 U.S. 113 (1973); and *Whalen v. Roe*, 429 U.S. 589 (1977) by the California Supreme Court are squarely in accord with the opinions of this Court. Since lack of accord with the decisions of this Court is the only rationale for review advanced by the Petitioner, the petition should be denied.

The California Supreme Court's decision is in accord with this Court's holding in *Planned Parenthood of Missouri v. Danforth* that choice among medical alternatives is not at this time a decision within the zone of constitutionally protected privacy.[2] There, this Court struck down a state prohibition of a particular abortion procedure, saline amniocentesis.[3] However, the Court did not hold that, because the right of privacy encompasses a woman's decision to have an abortion, the state may not prohibit a particular abortion procedure. Rather, citing *Roe v. Wade, supra,* the Court stated the issue before it as follows:

> "[W]hether the flat prohibition of saline amniocentesis is a restriction which 'reasonably relates to the preservation and protection of maternal health' ".[4]

[2] 428 U.S. 52 (1976).
[3] *Id.* at 79.
[4] *Id.* at 76.

The Court cited voluminous record evidence of the safety and effectiveness of saline amniocentesis, as compared with other available abortion procedures, and concluded that the state prohibition bore no reasonable relationship to the protection of maternal health. Significantly, in discussing the validity of the statutory prohibition of this particular medical procedure, the Court did not refer to any constitutional considerations of privacy. No such considerations were involved in the selection of that particular medical procedure by the patient and her physician. The procedure was evaluated by them and by the Court solely on the basis of the medical evidence of its safety and effectiveness.

Planned Parenthood thus stands for the proposition that although a decision of whether to have an abortion is within the constitutional zone of privacy, deserving the protection provided by the "compelling interest" standard, the selection of a particular abortion procedure is a medical matter to which privacy status does not attach and which may be regulated by government, provided a rational basis for such regulation exists.

In the instant case, the analogue of the right to decide whether to have an abortion is the right to decide whether to receive or forego cancer treatment. Although the decision whether to receive treatment may be constitutionally protected, the choice among treatment alternatives is not within the scope of the constitutional right to privacy. In *Planned Parenthood* the issue was whether the regulation reasonably relates to the preservation and protection of maternal health. Its analogue here is whether the premarketing provisions of the California statute reasonably

relate to the preservation and protection of the health of the cancer patient. The California Supreme Court correctly held that the state statute establishing a safety and efficacy standard reasonably relates to the preservation and protection of the health of cancer patients.

The decision by the California Supreme Court tracks the rationale expressed by this Court in *Roe v. Wade, supra,* in which this Court recognized that where public health and safety are at stake, even fundamental rights may be regulated and restricted under the state's police power.[5] While finding that the right of privacy is "broad enough to encompass a woman's decision whether or not to terminate her pregnancy",[6] the decision in *Roe* holds that at some point during pregnancy the state's important interest in safeguarding health, in maintaining medical standards, and in protecting potential life became sufficiently compelling to sustain regulation of the factors that govern the abortion decision.[7] With respect to the health of the mother, this Court concluded that the "compelling" point is at approximately the end of the first trimester.[8] This conclusion was based on the medical fact that the risk of a woman's death in first trimester abortions appears to be at least as low as that in normal child birth, while the increase in the hazards to abortion procedure in the second trimester justified imposition of state regulations. With respect to the state's interest in potential life, the compelling point was found to be at viability—which occurs approximately at the end of the second trimester. At this point this Court indicated that the state could even prohibit abortion except when necessary for the preservation of maternal life or health.[9]

[5] *Roe v. Wade,* 410 U.S. at 153-154, 162-163.
[6] *Id.* at 153.
[7] *Id.* at 154.
[8] *Id.* at 163.

These aspects of the holding in *Roe* are significant in light of the constitutional issue raised, for they reflect this Court's recognition of the government's compelling interest in protecting individual health, and in protecting the public health generally where individual conduct may adversely affect the well-being of others.[10] The authority to protect individual health, and the public health generally, may be exercised to overrule the woman's personal decision to undergo a particular medical or surgical procedure during the second and third trimesters of pregnancy even when she is fully aware of the risks of the procedure, and is willing to take those risks.[11] An individual's decision to use Laetrile can stand on no higher constitutional level than the decision of a woman to have an abortion in the later stages of pregnancy.

It has been established that a significant number of cancer patients can be cured or have their lives extended by the use of legitimate therapy, especially when treatment is begun as soon as possible after diagnosis.[12] The availability of Laetrile serves to encourage delay among

[9] *Id.*
[10] Even John Stuart Mill recognized that state regulation in the area of public health did not impermissibly infringe upon the choice of the individual. He contended that where, "there is a definite damage, or a definite risk of damage, either to an individual or to the public, the case is taken out of the province of liberty and placed in that of morality or law." J. S. Mill, On Liberty 100 (Liberty Arts Press 1956).
[11] 410 U.S. at 162-165.
[12] *E.g.,* The FDA rulemaking decision on laetrile, *Laetrile, Commissioner's Decision,* 42 Fed. Reg. 39768, 39782 (1977).

certain cancer patients in seeking effective therapy.[13] Moreover, even among patients who begin treatment of their cancers with effective therapy, the readily acknowledged side effects of that therapy may cause them to cease to use such methods at a time when their application still may be successful, and turn instead to Laetrile—"a painless cure".[14] Because legitimate therapy may be stopped, delayed or avoided, many cancer patients will die needlessly or prematurely. This fact alone provides compelling justification for prohibiting interstate transportation and sale of drugs such as Laetrile absent compliance with the premarketing standards that are contained in federal drug laws and California Health and Safety Code § 1707.1.

Finally, the California Supreme Court's decision closely tracks the state interest rationale set forth by this Court in *Whalen v. Roe, supra.* There, the Court upheld a state statute requiring physicians to report the names and addresses of patients for whom the physicians had prescribed certain dangerous drugs to a state agency. The patients contended, among other things, that the statute invaded their constitutionally protected zone of privacy by depriving them of the right to decide independently, with the advice of a physician, to acquire and use needed medication. The Court upheld the statute, citing cases using ordinary, not "compelling interest" tests for the exercise of the police power and concluded that the impact of the statute on either the reputation or the independence of patients for whom the specified drugs are medically indicated is not sufficient to constitute an invasion of any right

[13] *Id.* at 39799.
[14] *Id.* at 39797, 39799.

or liberty protected by the Fourteenth Amendment.[15] The Court also held that the physicians' claim is derivative from the patients' and must therefore fall along with the rejected patients' claim of protection.[16]

Furthermore, although the drugs involved in *Whalen* were narcotics and classified as dangerous drugs, they were safe and effective for their intended use by FDA standards. Thus they satisfied the standards which Dr. Privitera has tried to circumvent. To the same effect is *Eisenstadt v. Baird,* 405 U.S. 438 (1972), where this Court held that unmarried individuals have a privacy right to purchase and use contraceptives, but noted that the contraceptives themselves, if they are new drugs within the meaning of the Federal Food, Drug and Cosmetic Act, would be subject to pre-market approval and the safety and efficacy standard. Thus, the physician-patient relationship language of *Whalen* relied on by Petitioner is inapplicable. In *Whalen* the drugs had passed the safety and efficacy threshold and were "approved". The present case is distinct, as Laetrile has not been found safe or effective by the appropriate agency.

II.

THE RATIONALE OF THE CALIFORNIA SUPREME COURT'S OPINION IS IN ACCORD WITH THIS COURT'S DECISION IN UNITED STATES V. RUTHERFORD

This Court in *United States v. Rutherford,* ..... U.S. ....., 47 U.S.L.W. 4724 (1979), expressly held that the federal drug law standards of safety and efficacy, which corre-

[15] 429 U.S. at 603-604.
[16] *Id.* at 604.

spond with the California statutory provisions, bear a reasonable relationship to the terminal patient, which is the context on which most cancer patients are viewed by the general public.[17]

> . . . Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs.
>
> A drug is effective within the meaning of § 201(p)(1) if there is general recognition among experts, founded on substantial evidence, that the drug in fact produces the results claimed for it under prescribed conditions. See *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S., at 629-634; n. 7 *supra*. Contrary to the Court of Appeals' apparent assumption, see 582 F.2d at 1236, effectiveness does not necessarily denote capacity to cure. In the treatment of any illness, terminal or otherwise, a drug is effective if it fulfills, by objective indices, its sponsor's claims of prolonged life, improved physical condition, or reduced pain. See 42 Fed. Reg. 39776-39786.

[17]This popular belief contrasts strongly with the actual statistics relating to survival from cancer due to earlier diagnosis and the steady improvement in surgical, x-ray and chemical approaches to the management of cancer. In the 1900's few cancer patients had any hope of long-term survival. In the 1930's less than one-in-five were alive at least five years after treatment. In the 1950's it was one-in-four. Now the ratio of patients alive after five years of disease is one in three. With even earlier diagnosis and proper treatment, half of those who have cancer could be saved. See American Cancer Society, *1977 Cancer Facts & Figures*.

The importance of early detection and treatment in terms of survival when cancer is localized as opposed to delay in treatment until the cancer has spread is set forth in the American Cancer Society, *1979 Cancer Facts & Figures* at page 9. The chart shows the following five year survival rates for localized as compared to disseminated cancer: bladder 72/14; breast 85/47; colon-rectum 71/26; larynx 79/32; lung 33/4; oral 67/25; prostate 70/35; uterus-cervix 78/37; and uterus corpus 86/33.

> So too, the concept of safety under § 201(p)(1) is not without meaning for terminal patients. Few if any drugs are completely safe in the sense that they may be taken by all persons in all circumstances without risk. Thus, the Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use. For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit. . . .
>
> Moreover, there is a special sense in which the relationship between drug effectiveness and safety has meaning in the context of incurable illnesses. An otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect. See 107 Cong. Rec. 5640 (1961) (comments of Sen. Kefauver). But if an individual suffering from a potentially fatal disease rejects conventional therapy in favor of a drug with no demonstrable curative properties, the consequences can be irreversible. . . .
>
> . . . To accept the proposition that the safety and efficacy standards of the Act have no relevance for terminal patients is to deny the Commissioner's authority over all drugs, however toxic or ineffectual, for such individuals. If history is any guide, this new market would not be long overlooked. Since the turn of the century, resourceful entrepreneurs have advertised a wide variety of purportedly simple and painless cures for cancer, including lineaments of turpentine, mustard, oil, eggs, and ammonia; peatmoss; arrangements of floodlamps; pastes made from glycerin and limburger cheese; mineral tablets; and "Fountain of Youth" mixtures of spices, oil and suet. . . .
>
> We note finally that construing § 201(p)(1) to encompass treatments for terminal diseases does not

> foreclose all resort to experimental cancer drugs by patients for whom conventional therapy is unavailing. Section 505(i) of the Act, 21 U.S.C. § 355(i), exempts from premarketing approval drugs intended solely for investigative use if they satisfy certain preclinical testing and other criteria . . .[18]

Thus this Court in *Rutherford,* construing a statute which provides the same protection as the California statute, found a reasonable relationship between the protections provided and the cancer patient. The California Supreme Court's application of the reasonable relationship test is in accord with the decision in *Rutherford.*

Petitioner argues that Laetrile is not toxic[19] and is harmless when used by cancer victims.[20] Apparently petitioner is arguing that Laetrile is safe and/or effective. However, the issue of Laetrile's safety or efficacy was specifically not addressed by the California Supreme Court.[21] The issue decided by the California Supreme Court was whether the statutory scheme establishing a standard of safety and efficacy is a reasonable exercise of the police power.

While it is not an issue properly before this Court, amicus curiae cannot overlook the false premise advanced in the petition that Laetrile is not toxic. In reality the great weight of authority is to the contrary. Medical re-

[18]Slip opinion at pp. 10-13, 47 U.S.L.W. at 4727-4728.

[19]Petition for Writ of Certiorari at 12, 22.

[20]*Id.* at 13, 15 and 17.

[21]*People* v. *Privitera,* 23 Cal.3d at 708.

searchers,[22] courts,[23] and the Food and Drug Administration[24] have all gathered evidence of Laetrile's toxicity.

The petitioner also argues that Laetrile is a "less hazardous" treatment than conventional cancer therapy, and in effect that it is harmless when used by cancer victims, and therefore less regulation is permissible since the treatment itself is not harmful.[25] This overlooks the rationale underlying the safety and efficacy requirements of state and federal law. Where drugs utilized for life-threatening illness are involved, safety is equated with efficacy because the treatment of a life-threatening illness with an ineffective drug may delay the initiation of effective therapy until the disease is beyond control. *Durovic v. Richardson,* 479 F.2d 242, 250 (7th Cir. 1973), *cert. den.,* 414 U.S. 944. As this Court stated in *United States v. Rutherford, supra:*

> ". . . An otherwise harmless drug can be dangerous to any patient if it does not produce its purported therapeutic effect (Citation omitted.) But if an individual suffering from a potential fatal disease rejects conventional therapy in favor of a drug with no demonstrable

[22]*E.g.,* Lewis, "Laetrile", 127 Western Journal of Medicine 55 (July, 1977); Jukes, "Laetrile for Cancer", 236 Journal of the American Medical Ass'n. 1284 (Sept. 13, 1976); Hambert, "Fatal Cyanide Poisoning: Accidental Ingestion of Amygdalin", 238 J. AMA 482 (Aug. 8, 1977); Smith, et al., "Laetrile Toxicity: A Report of Two Cases", 238 J. AMA 1361 (Sept. 13, 1976). *See also,* Comment, "Laetrile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs", 127 U. Pa. L. Rev. 233, 246-249 (1978), and materials cited.

[23]*United States v. General Research Laboratories,* 397 F. Supp. 197, 198-199 (C.D. Cal. 1975) (toxicity); *cf. United States v. Spectro Foods Corp.,* Civ. No. 76-101 (D.N.J.), *aff'd in part, rev'd in part,* 544 F.2d 1175 (3d Cir. 1976) (adulterated and misbranded).

[24]42 Fed. Reg. 39767, 39768 (1977).

[25]Petition for Writ of Certiorari at 15, 17.

curative property the consequences can be irreversible . . ."[26]

Thus, the decision by the California Supreme Court is in accord with prior decisions of this Court. To the extent the petition attempts to raise the issue of whether Laetrile itself is safe or effective in treating cancer, it misconstrues the issues before this Court.

CONCLUSION

The California Supreme Court's interpretation of Health and Safety Code § 1707.1 is consistent with the opinions rendered in analogous cases by this Court. The decision by the California Supreme Court is in keeping with the principles enunciated by this Court, and reinforces the protections provided by state and federal law for patients with life-threatening illness. For these reasons, Dr. Privitera's petition should be denied.

Dated July 11, 1979

Respectfully submitted,

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[26]Slip Opinion at 11; 47 U.S.L.W. at 4727. See Justice Douglas' opinion in *Ewing v. Mytinger & Casselberry, Inc.*, 339 U.S. 594, 599-600 (1950) ("[Congress] may conclude . . . that public damage may result even from harmless articles if they are allowed to be sold as panaceas for man's ills . . .").